UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF TEXAS

| UNITED STATES OF AMERICA ex rel. BROOK JACKSON, |) |
|---|---------------------------------------|
| Plaintiff, |)) |
| v. |) Civil Action No.: 1:21-cv-00008-MJT |
| VENTAVIA RESEARCH GROUP, LLC; PFIZER, INC.; ICON PLC |))) |
| Defendants. |)) |

ICON PLC'S NOTICE OF JOINDER IN PFIZER'S MOTION TO STAY DISCOVERY

Under Federal Rule of Civil Procedure 10(c), Defendant ICON PLC ("ICON") hereby incorporates by reference and joins Pfizer's Motion to Stay Discovery and Memorandum in Support [ECF No. 40] ("Pfizer's Motion") and provides herein additional bases supporting a stay of discovery.

In addition to the reasons stated in Pfizer's Motion, the Court should stay discovery with regard to ICON because Relator falls far short of pleading *any* viable claims against ICON with sufficient particularity. As will be explained further in ICON's forthcoming Motion to Dismiss Relator's Amended Complaint, Relator's few allegations against ICON—which appear to be nothing more than an afterthought—come nowhere close to satisfying the heightened pleading standard imposed by Federal Rule of Civil Procedure Rule 9(b). Those heightened pleading standards were designed to protect defendants from precisely what discovery at this early point in the case would be: a fishing expedition based entirely on meager, generic, and conclusory allegations of fraud. Courts have recognized the particular import of Rule 9(b) in False Claims Act cases, where the relator must be an "insider" with independent knowledge of the alleged

wrong in order to satisfy the statutory prerequisites to bringing a claim. Allowing discovery to proceed while ICON's motion to dismiss is pending would thwart Rule 9(b)'s critical function as a gatekeeper to discovery. ICON respectfully requests that the Court stay all discovery pending a decision on the adequacy of Relator's pleadings.

ARGUMENT

In addition to the points raised by Pfizer's Motion, which ICON expressly joins and incorporates by reference, a stay of discovery should be granted because early discovery is disfavored prior to the court's evaluation of the sufficiency of fraud allegations, particularly those brought under the False Claims Act. The pleadings themselves demonstrate that the claims asserted against ICON are at most an afterthought, which find no factual or legal support in the Amended Complaint's anemic allegations. Relator does nothing more with regard to ICON than allege "constructive notice" of alleged misconduct. Such allegations are plainly insufficient to state a False Claims Act claim, and Relator's deficient pleading only confirms the implausibility of her claim by alleging that the purportedly false information was "hidden away" by defendant Ventavia Research Group, LLC ("Ventavia") in "notes to the file" or source documents. (Am. Compl. ¶¶ 8, 169, 191). Relator nowhere explains how her allegations that ICON was on constructive notice of wrongdoing can be reconciled with her allegations that others hid such information from ICON. Moreover, despite elsewhere acknowledging that her experience at test sites spanned mere days and was "limited to Texas," Relator speculates that "Pfizer and ICON's oversight failures and fraudulent misconduct vis-à-vis Ventavia bring the entire Pfizer BioNTech clinical trial into question," and that "[i]t is likely that similar fraud occurred at clinical trial sites managed by other subcontractors of Pfizer." (Am. Compl. ¶ 11).

As will be described further in ICON's forthcoming Motion to Dismiss Relator's Amended Complaint, these allegations against ICON fall far short of the standard required by Rule 9(b). See United States ex rel. Steury v. Cardinal Health, Inc., 2011 WL 13266915, at *3, 6 (S.D. Tex. Aug. 29, 2011), report and recommendation adopted, 2011 WL 13266916 (S.D. Tex. Sept. 27, 2011) (holding that claims brought under the False Claims Act must satisfy the heightened pleading requirements of Rule 9(b), a more strict standard than Rule 8). The small number of allegations against ICON are generalized, conclusory, or speculative, and cannot state a plausible claim.¹ For example, Relator alleges that ICON missed "red flags" of trial protocol violations and that errors would have been obvious from source documents, but does not state with "particularity" which red flags ICON missed, how the violations were obvious, or the identity of the source documents. United States ex rel. Spicer v. Westbrook, 751 F.3d 354, 365, 367 (5th Cir. 2014); see also U.S. ex rel. Ruscher v. Omnicare, Inc., 2014 WL 2618158, at *9 (S.D. Tex. Jun. 12, 2014), on reconsideration in part sub nom. Ruscher v. Omnicare Inc., 2014 WL 4388726 (S.D. Tex. Sept. 5, 2014) (holding that a relator who seeks to advance a False Claims Act claim must provide factual content establishing the "who, what, where, when and how" as to each of the specific elements of the cause of action). In fact, the Amended Complaint is littered with contrary allegations that information was purposefully withheld from ICON; a curiosity that demonstrates the frivolity of Relator's claims against ICON. (Am. Compl. ¶¶ 29, 150, 157, 161, 169, 176, 178, 183-84, 196-97, 201, 205, 251, 254).

¹ Allowing discovery at this stage would also be inappropriate because the Amended Complaint lacks a sufficient basis to claim that ICON plc, "an Irish company headquartered in Dublin" (Am. Compl. ¶ 45), is even the relevant ICON corporate entity in this action.

I. <u>Discovery Should be Stayed to Preserve Rule 9(b)'s Screening Function</u>

It is black letter law that "Rule 9(b) has long played [a] screening function, standing as a gatekeeper to discovery, a tool to weed out meritless fraud claims sooner than later." United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 185 (5th Cir. 2009); see also Nunnally v. W Calcasieu Cameron Hosp., 519 F. App'x 890, 892 n.2 (5th Cir. 2013) ("Rule 9(b)'s requirement for pleading with particularity . . . prevents discovery intended as a mere fishing expedition . . ."); United States ex rel. Atkins v. McInteer, 470 F.3d 1350, 1359 (11th Cir. 2006) ("The particularity requirement of Rule 9 is a nullity if Plaintiff gets a ticket to the discovery process without identifying a single claim."). As the Fifth Circuit emphasized in *Grubbs*, Rule 9(b)'s objectives included "prevent[ing] plaintiffs from filing baseless claims [and] then attempting to discover unknown wrongs," and concluded that, "[u]ltimately the question is what is required for a ticket to the federal discovery apparatus." 2 Grubbs, 565 F.3d at 190. These considerations carry particular import in the context of a qui tam False Claims Act case, which may be brought only by insiders with unique knowledge of the alleged fraud. See United States ex rel. Schutte v. Supervalu, Inc., 2016 WL 3906570, at *1 (C.D. Ill. Jul. 14, 2016) ("The Relators in this False Claims Act action must allege fraudulent violations with the particularity required by Rule 9(b). The heightened pleading standard requires a relator to make a more extensive investigation before bringing claims of fraud. That purpose would be frustrated 'by allowing a relator to make vague claims of fraud, and then permitting him to engage in discovery in the hope of uncovering enough specifics to adequately plead a case."") (citations omitted).

² It is clear that Relator's claims against ICON are nothing more than a pretext for a fishing expedition. Despite naming ICON as a defendant, Relator did not identify a single person from ICON as someone with knowledge of discoverable facts in her Initial Mandatory Disclosures and will not suffer any prejudice as a result of the requested discovery stay.

Where a defendant has (or, in ICON's case, shortly will) raise serious concerns in a motion to dismiss regarding Relator's failure to plead fraud claims with sufficient particularity, the Court should stay discovery in order to preserve Rule 9(b)'s critical gatekeeping function. Courts frequently grant stays of discovery when faced with similarly clear failures to meet Rule 9(b)'s pleading standards. See, e.g., United States ex rel. Liotine v. CDW-Government, Inc., 2009 WL 720958, at *1, 3 (S.D. Ill. Mar. 18, 2009) (granting a stay of discovery in an FCA action where a motion to dismiss for failure to plead with particularity was pending, because the "purpose of the heightened pleading requirement . . . is frustrated by allowing a relator to make vague claims of fraud, and then permitting him to engage in discovery in the hope of uncovering enough specifics to adequately plead a case"); United States ex rel. Lusby v. Rolls-Royce Corp., 2007 WL 4557773, at *2 (S.D. Ind. Dec. 20, 2007) (discovery stayed in an FCA action pending a decision on defendant's motion for judgment on the pleadings for lack of particularity under Rule 9(b)); see also Pennington v. Vail Products, Inc., 2004 WL 302298, at *1-2 (N.D. Tex. Jan. 8, 2004) (denying plaintiffs' request for "minimal discovery" and granting motion to dismiss, noting that "[f]raud claims must be averred with specificity *before* discovery is undertaken") (emphasis added).

The Amended Complaint says considerably more about what was *hidden* from ICON than what ICON allegedly did, instead falling back on conclusory and unsupported assertions that ICON missed "red flags" of trial protocol violations. This falls far short of Rule 9(b)'s screening requirements. As such, a stay of discovery is particularly warranted here, due to the abject sparsity of any allegations—much less allegations pleaded with particularity—against ICON.

CONCLUSION

For the foregoing reasons, and the reasons stated in Pfizer's Motion to Stay Discovery, good cause exists to stay all discovery in this matter pending the Court's rulings on ICON's forthcoming motion to dismiss.

Date: May 18, 2022 Respectfully Submitted,

/s/ Scott L. Davis

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CERTIFICATE OF SERVICE

I hereby certify that on May 18, 2022 a true and correct copy of the foregoing document was served upon all counsel of record via the Court's CM/ECF system in accordance with this Court's Local Rules.

/s/ Scott L. Davis
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